

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the efficacy of different doses of buprenorphine (8mg, 2mg) on the reduction of methamphetamine withdrawal symptoms, depression, suicidal thought and anxiety.

Protocol summary

Summary

The aim of this trial is to compare the effect of buprenorphine (8mg, 2mg) in reduction of methamphetamine craving, depression, suicidal thought and anxiety. In this double blind trial at least 66 inpatients will be selected and by random sampling will be divided to three groups and each group includes at least 22 patients. Each group receives buprenorphine 8 mg or 2 mg or placebo for a period of at least five days. We evaluate the craving of patients by interview and questionnaire every day to find more effective medication. Inclusion criteria: Age between 18 to 60; They are free to participate in the study; Patient's major substance use be methamphetamine. Exclusion criteria: Patients unwilling to participate at beginning or during the study; Use of another substance except Methamphetamine as of the main substance.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017081525160N8**

Registration date: **2017-08-25, 1396/06/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-25, 1396/06/03

Registrant information

Name

Jamshid Ahmadi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3627 3070

Email address

ahmadij@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2017-08-15, 1396/05/24

Expected recruitment end date

2018-10-16, 1397/07/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of different doses of buprenorphine (8mg, 2mg) on the reduction of methamphetamine withdrawal symptoms, depression, suicidal thought and anxiety.

Public title

Comparison of the efficacy of different doses of buprenorphine (8mg, 2mg) on the reduction of methamphetamine(crystal, Shishe) withdrawal symptoms, depression, suicidal thought and anxiety

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age: 18-60 ;informed consent; methamphetamine dependence Exclusion criteria:Patients unwilling to participate at beginning or during the study; use of another substance except

Methamphetamine as of the main substance.

Age

From **18 years** old to **60 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand blvd

City

Shiraz

Postal code

7194634786

Approval date

2017-08-01, 1396/05/10

Ethics committee reference number

IR.SUMS.REC

Health conditions studied**1****Description of health condition studied**

Methamphetamine Dependency

ICD-10 code

F15

ICD-10 code description

Mental and behavioural disorders due to use of other stimulants, including caffeine

Primary outcomes**1****Description**

Craving, depression, suicidal thoughts and anxiety

Timepoint

Daily for 5 days

Method of measurement

Questionnaire and interview

Secondary outcomes

empty

Intervention groups**1****Description**

We will use buprenorphine 8mg sublingual daily for one group for at least 5 days

Category

Treatment - Drugs

2**Description**

We will use buprenorphine 2 mg sublingual daily for the other group at least 5 days.

Category

Treatment - Drugs

3**Description**

We will use placebo sublingual daily for one group for at least 5 days

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

EbneSina Hospital

Full name of responsible person

Jamshid Ahmadi M.D

Street address

EbneSina Hospital, Hafeziye street

City

Shiraz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

SayedBasirHashemi

Street address

vice Chancellery for Research Affairs, Shiraz
University of Medical Sciences, Zand Blvd

City

Shiraz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

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Professor

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Fax**Email****Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty